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February 19, 2013

Certified Mail #7012 1010 0000 1631 2485

Ms. Debra Van Putten
14364 Clearview Avenue
Gainesville, VA 20155

Subject:	Patient:	Van Putten, Sharon
	Facility:	Inova Fair Oaks Hospital and Inova Fairfax Hospital
	Provider #:	490101 and 490063
	HIC #:	333361603A
	Dates:	Inova Fair Oaks Hospital: 6/27/11 and 6/30/11, Inova Fairfax Hospital: 7/1/11-7/21/11, 8/17/11-8/18/11, and 8/29/11-9/27/11
	CK#s:	10784123,10784124,10785275,10771647, and 10793630

Dear Ms. Van Putten:

We have completed our review of your written complaint. As you are aware, VHQC is the Quality Improvement Organization (QIO) authorized by the Medicare program to review medical services provided to Medicare patients in the Commonwealth of Virginia. When we review written complaints about the quality of Medicare services received by Medicare patients, our responsibilities include a thorough review of medical records to determine whether the services meet medically acceptable standards of care, are medically necessary, and are delivered in the most appropriate setting. When we confirm a quality concern, we provide education to health care facilities, physicians, and other medical staff to improve the quality of care that they deliver to beneficiaries.

In response to your written concerns, QIO physician reviewers have carefully reviewed the medical records regarding the services your mother, Sharon Van Putten, received on June 27, 2011 and June 30, 2011 at Inova Fair Oaks Hospital in Fairfax, Virginia, and on July 1, 2011 through July 21, 2011, August 17, 2011 through August 18, 2011, and on August 29, 2011 through September 27, 2011 at Inova Fairfax Hospital in Falls Church, Virginia. Before reaching our decision, we gave all of the involved hospitals and physicians an opportunity to review our response concerning the services your mother received. Please see the attached comments provided by Inova Fairfax Hospital in regards to our findings.

After a thorough review of the medical records and of any additional information provided by the physicians or hospitals, we determined the following:

VHQC Review Findings:

According to the medical record, your mother underwent a CTA of the chest to determine if she had a pulmonary embolus (blood clot) in her lung. The test was negative for an embolus, but revealed a nodule in the left upper lobe of the lung measuring 1.8 cm x 1.3 cm. It was noted on the Inova Fair Oaks Hospital patient discharge instructions that the family was informed of the nodule in your mother's lung. The discharge instructions also included the following physician note, "Your left lung nodule will need to be followed up by your regular physician in Michigan." Per the medical record, on June 29, 2011, an Inova Fair Oaks physician called and spoke with your mother's husband about her CTA results. The note states, "Spoke to husband of the patient who is very involved in her care, knew of pulmonary nodule. Patient has had many prior imaging tests, and husband felt this not to be new, but he will continue to follow up with her primary care physician over time."

In the opinion of the VHQC physician reviewer, the family was notified of the nodule in your mother's lung at discharge and again on June 29, when the physician called and spoke to her husband. Her husband responded that they were aware of the nodule and would continue to follow up with your mother's primary care physician. Therefore, no quality of care concern was found for this stated complaint.

Based on a review of the medical documentation regarding this concern, we determined that the services received **did** meet all applicable professionally recognized standards of health care.

Your concern regarding your mother's care at Inova Fair Oaks Hospital on June 30, 2011:

- ❑ You state your mother was discharged too soon from the Emergency Department (ED) on June 30, 2011. You felt she should have been admitted to the hospital.

VHQC Review Findings:

According to the medical record, your mother came to the ED on June 30, 2011 with difficulty breathing and increasing lower extremity weakness. Per the nursing note, your mother was experiencing labored breathing. The nurse also noted your mother had good strength in all of her extremities and that her feet were twitching. According to the medical record, your mother reported pain at a level of nine out of ten. The ED staff medicated her with intravenous Dilaudid. Because family members told the ED staff that your mother had been hallucinating for two days, a CAT scan of her head was completed, which showed no acute findings.

A chest x-ray was performed which revealed "stable spinal rods along the entire thoracic spine." Per the physician's note, the family expressed concern about your mother going home because she could not stand. The chart indicated that your mother then demonstrated that she could stand, but needed assistance with walking. The note reflected that your mother would be

admitted for further evaluation of her confusion, but "at that time, the patient began crying and stated that she did not want to be admitted, but she just wanted narcotics."

The physician noted he would still admit your mother though he also noted "the family members were frustrated as the patient was refusing to be admitted." "They became more angry as the patient cried asking for more narcotics. He (your mother's husband) then demanded discharge and refused to have the patient admitted." Further, per an ED physician note, "We'll be happy to admit her to the hospital should they return or if they want her reevaluated then they should return to the Emergency Department."

In the opinion of the VHQC physician reviewer, your mother was evaluated by the physician who was going to admit her to the hospital because of her confusion. However, the documentation supports that both your mother and the family declined admission to the hospital on June 30, 2011. Therefore, no quality of care concern was found for this stated complaint. Based on a review of the medical documentation regarding this concern, we determined that the services received **did** meet all applicable professionally recognized standards of health care.

Your concerns regarding your mother's care at Inova Fairfax Hospital from July 1, 2011 through July 21, 2011:

Your Concern:

- ❑ You state there was a delay in completing your mother's surgery.

VHQC Review Findings:

Per the medical record, your mother was transferred to Inova Fairfax Hospital from another Emergency Department (ED) on July 1, 2011 to be evaluated for leg weakness and back pain. Upon arrival, it was noted that your mother was unable to walk due to pain, unable to lift her legs, and had decreased rectal muscle tone per physical exam. Her medical history was documented as significant for multiple previous back surgeries, pulmonary fibrosis and chronic obstructive pulmonary disease (COPD). On July 2, 2011, your mother underwent a thoracic spine level 3-7 decompression with exploration of a previous fusion at thoracic level 2-7 with hardware removal from thoracic level 2-6, posterior segmental fixation from thoracic level 2-7, and arthrodesis (surgical fusion) of thoracic level 2-7. Per the documentation in the medical record, it was noted that the hardware from a previous surgery was not intact. Post-operatively, your mother did not regain movement in her legs. During her recovery, your mother developed a urinary tract infection (UTI) and had periods of delirium and agitation. Additionally, she experienced respiratory distress, resulting in her having to be intubated and placed on a ventilator for a period of time. Per the record, she stabilized and was discharged to an inpatient rehabilitation facility on July 21, 2011 with an improved respiratory status.

Per the medical record, MRI (magnetic resonance imaging) studies of the lumbar, thoracic and cervical spine were ordered while your mother was in the ED. At approximately 9:30 am on July 1, 2011, your mother's lumbar MRI was completed, but it did not yield viable information due to artifact. This artifact noted refers to the metallic rods and screws present from her previous surgeries. MRI studies of your mother's cervical and thoracic spine were ordered at approximately 1:20 pm on July 1. According to the medical record, the MRI studies of your mother's cervical and thoracic spine were attempted, but could not be completed as your mother was in pain and unable to lie still.

The documentation of July 1 reflects that both a CAT myelogram (injection of x-ray dye into the spinal sac followed with a CAT scan to view spinal nerve roots) and MRIs were indicated. One note reflects that the CAT myelogram was necessary to diagnose whether the cause of your mother's paraplegia (impairment in motor or sensory function of the lower half of a person's body) was spinal cord compression or secondary to a neurological condition, such as inflammation. However, other documentation indicated that it was felt the MRIs should be completed first, even though the lumbar MRI was inconclusive due to artifact. The cervical and thoracic MRIs were later done. The record indicates in a note dated July 1 at 11:30 pm that the myelogram was attempted though aborted at 11:00 pm. The myelogram was later performed and completed at 4:45 am on July 2, and revealed a significant block in the contrast flow in your mother's spine. The record indicates that your mother's surgery began at 9:12 am on July 2.

In the opinion of the VHQC physician reviewer, it is difficult to determine exactly when your mother progressed to paraplegia (complete paralysis of the lower half of the body including both legs, usually caused by damage to the spinal cord) prior to surgery. Rapid reversal of compressive pathology is critical to reversing neurologic decline due to spinal cord compression. A MRI is the best and quickest screen for spinal cord pathology, and both the cervical and thoracic MRIs should have been done. However, given the hardware from previous spinal surgeries, the lumbar MRI findings were not useful. Performing a thoracic MRI was not appropriate after a lumbar study showed too much artifact to read accurately. Once the lumbar MRI revealed artifact from instrumentation, CAT myelogram should have been the next test completed, not an attempt at a thoracic MRI. The myelogram offered the best chance to see where the pathology was localized. Additionally, the documentation was poor regarding the cause of the delay in completing your mother's myelogram and it appears this led to further delay in the proper diagnosis and treatment of your mother.

Based on a review of the medical documentation regarding this concern, we determined that the services received **did not** meet all applicable professionally recognized standards of healthcare. We share your concern about the quality of service your mother received.

Your Concern:

- ❑ You state your mother was to be tapered off steroids after surgery, but this was not done.

VHQC Review Findings:

Per the medical record, your mother had been taking oral steroids (Prednisone 6 mg daily) prior to her surgery. Post-operatively, she was started on Decadron 4 milligrams every six hours, either orally or in her intravenous line. Decadron was discontinued on July 13 and on this date, she was started on oral Prednisone at a dose of 40mg per day. On July 17, your mother's Prednisone dose was tapered to 15mg a day for two days, then 10mg for two days, then 6mg a day. According to the record, your mother remained on Prednisone throughout her stay.

Per the VHQC physician reviewer, the decision to taper steroids after surgery is dependent on a host of factors. Certainly, chronic use of steroids can lead to the increased risk of post-surgical complications. This situation was made more complex by the fact that your mother was on chronic longstanding Prednisone therapy prior to her surgery. The medical record reflects that the steroids were eventually weaned back to her preadmission dose of Prednisone 6mg per day. In the opinion of the VHQC physician reviewer, it appears the length of time your mother was on the steroids did not impact her course or outcome, and her steroids were tapered to her preoperative dose of 6mg a day. Therefore, no quality of care concern has been found for this stated complaint.

Based on a review of the medical documentation regarding this concern, we determined that the services received **did** meet all applicable professionally recognized standards of health care.

Your Concern:

- ❑ You state your mother's discharge summary did not contain information regarding her lung nodule.

VHQC Review Findings:

Per the medical record, your mother underwent a CTA on June 27, 2011 during an Emergency Department (ED) visit at Inova Fair Oaks Hospital as part of an evaluation to rule out a pulmonary embolus (blood clot in the lung). The results showed a 1.8 cm x 1.3 cm nodule in her left lung. Per the ED note, the family was informed of the nodule at that time. She had another CTA on July 10, 2011 during this hospitalization which revealed "mild mediastinal lymphadenopathy (enlargement of the mediastinal lymph nodes) has progressed with nodes measuring up to 2 cm." Follow-up was recommended by the radiologist. According to the medical record, no additional studies were performed related to the lung nodule. Also, there was no documentation found in the discharge summary noting the nodule or that follow-up was indicated.

In the opinion of the VHQC physician reviewer, the discharge summary should have addressed your mother's lung nodule. Although the medical record indicated that your mother's spouse was aware of the nodule, and the need for outpatient follow up, it would have helped future

caregivers if the discharge summary had included a plan for work-up of the nodule. Therefore, this quality of care concern has been confirmed. However, in the opinion of the VHQC physician reviewer, it was appropriate not to pursue additional testing related to the nodule during this inpatient hospital stay as your mother was critically ill during this hospitalization.

Based on a review of the medical documentation regarding this concern, we determined that the services received **did not** meet all applicable professionally recognized standards of health care. We share your concern about the quality of service your mother received.

Your Concern:

- ❑ You state your mother was septic during this hospital stay and it was not diagnosed.

VHQC Review Findings:

Per the medical record, a physician evaluated your mother on July 10, 2011 due to respiratory distress. She also had a low grade fever of 100.3°F earlier in the day and a urinalysis and intravenous antibiotics were ordered. The results of the urinalysis indicated that your mother had a urinary tract infection (UTI). Your mother was diagnosed with "severe sepsis with acute respiratory failure." Following the Adult Sepsis Order Set Physician Order form, blood, urine, and sputum cultures, as well as other blood work, were ordered.

The VHQC physician reviewer noted that your mother had a low grade fever on July 10 and noted that the physician ordered cultures to see if your mother had an infection. According to the medical record, initially antibiotics were withheld because her elevated white blood cell count (17 x 10 9/L) was attributed to the steroids she was taking. The results of the urinalysis indicated that your mother had a urinary tract infection and she was started on intravenous Vancomycin. When the sensitivity results came back, her antibiotic was changed to Ciprofloxacin. Sensitivity testing shows what type of bacteria are causing the infection, and which antibiotic best treats the infection. In the opinion of the VHQC physician reviewer, when your mother was found to have a low grade fever, cultures were appropriately ordered and antibiotics were started to treat her infection or sepsis. Therefore, no quality of care concern has been found for this stated complaint. Based on a review of the medical documentation regarding this concern, we determined that the services received **did** meet all applicable professionally recognized standards of health care.

Your Concern:

- ❑ You state your mother developed a decubitus ulcer during this hospital stay.

VHQC Review Findings:

According to the medical record, your mother did develop a decubitus or pressure ulcer on her sacrum. Post-operatively, your mother was on bed rest with the head of her bed elevated at 30

degrees. On July 3, 2011, your mother was noted to have Stage I skin breakdown on her sacrum. A Stage I ulcer is described as skin that has redness and that blanches with pressure; the skin is warm and soft to the touch. According to the medical record, a wound care consultation was ordered and on July 7, the certified wound care specialist attempted to evaluate your mother's ulcer. Although this evaluation initially was declined by your mother, it was completed on July 8. The wound was described as 5.0 cm x 4.0 cm, with the majority of the lesion red and non-blanchable with small blisters, and it was then classified as a Stage II ulcer. A Xenaderm dressing was ordered to increase blood flow and to provide moist wound healing. On July 14, the wound specialist noted that your mother's skin breakdown was likely due to friction from repositioning. There were no measurements noted. The note of July 19 from the wound care specialist described the ulcer as "unstageable" and measuring 2.0 cm x 1.0 cm eschar (dead tissue); deep tissue injury with 6.0 cm x 3.0 cm in various stages of healing, pink to light pink. Per the nursing notes, your mother was turned (repositioned in bed) every two hours and dressing changes were completed as ordered.

The hospital was queried about what was done to prevent your mother's skin breakdown, and what wound care was provided to prevent the ulcer's progression. The hospital's Quality Director responded that they were aware that your mother was at risk for skin breakdown and provided a therapeutic mattress, daily skin assessments, turning every two hours, elevating her heels, and moisture management. After the wound care assessment on July 8, dressing changes to promote healing were initiated every 12 hours. Also per the facility's response, a discrepancy was noted in the measurement of your mother's wound, specifically on July 19. The facility's Quality Director noted that your mother's sacral wound measured 0.2 cm x 0.1 cm and 0.6 cm x 0.3 cm on July 19, but the nurse documented that the wound measured 2 cm x 1 cm and 6 cm x 3 cm.

In the opinion of the VHQC physician reviewer, your mother was at high risk for this type of ulcer. She was paraplegic, had chronic steroid use, and a prolonged postoperative course with wound drainage. However, decubitus ulcers should not occur in the hospital setting if proper precautions and care are rendered. The use of a specialty care mattress and diligent repositioning are critical to prevent the development of these types of ulcers. This likely could have been a preventable complication. Therefore, this quality of care concern was confirmed for the hospital.

Based on a review of the medical documentation regarding this concern, we determined that the services received **did not** meet all applicable professionally recognized standards of health care. We share your concern about the quality of service your mother received.

Your Concern:

- ❑ You state your mother was restrained illegally during this hospital stay.

VHQC Review Findings:

Per the medical record, your mother's wrists were restrained at various times during her stay. The nursing notes indicate that your mother had episodes of agitation which interfered with her treatment. For example, she pulled out her Foley (urinary) catheter and took off her oxygen mask, causing her oxygen levels to fall. Some of these incidents occurred when family or staff were in her room. According to the record, medications were ordered to help calm your mother, but the family declined them. The medical record documentation supports that an order was received from the physician and the family was notified of the need for restraints. The nursing notes support that the restraints were removed while the family was in her room.

In the opinion of the VHQC physician reviewer, the use of restraints to prevent harm is not inappropriate. Your mother was at risk for self-harm due to her agitation and confusion, so to prevent additional self-harm, restraints were indicated. Apparently the family did not want to use medication to calm her, so physical restraints were utilized, especially when she was pulling out her catheter and trying to remove her oxygen mask. Therefore, no quality of care concern has been found for this stated complaint. Based on a review of the medical documentation regarding this concern, we determined that the services received **did** meet all applicable professionally recognized standards of health care.

Your Concern:

- ❑ You state your mother was given Haldol after the family requested she not be given this medication.

VHQC Review Findings:

A psychiatric consult was completed on July 7, 2011 and noted that your mother was being evaluated for her depressed and labile (shifting, changing) moods. The documentation states that your mother's symptoms were consistent with delirium. The note also reflected that the family stated her symptoms may be due to the addition of Neurontin several days prior, noting she had a similar reaction to Lyrica in the past. The Neurontin was discontinued on July 7 at that time.

According to the record, your mother was re-evaluated several hours later, and was noted to be more agitated and confused than earlier. The physician ordered Haldol 2mg every 12 hours as a standing order and every 12 hours as needed for agitation. On July 10, a note in the medical record indicated that the family did not want your mother to receive any further doses of Haldol and it was discontinued. The record indicated that on July 12 a new order for "Haldol 2.5mg now" was written. On July 13, the physician orders indicated Haldol was again discontinued as "the patient has an allergy to it per the family." The physician clarified that the patient had a "paradoxical agitation" (opposite effect than what was expected and the etiology is unknown) from the Haldol.

In the opinion of the VHQC physician reviewer, it was noted in the medical record that the family requested your mother no longer receive Haldol because of concerns that she might have an adverse reaction. There was no indication that the patient had been on Haldol before, and no documentation that the patient had a history of allergy or adverse reaction to Haldol. While the family did not want her to receive additional Haldol after it was discontinued on July 10, apparently, the patient was agitated on July 12 and Haldol was used to settle her. There was no indication of an allergy or of an allergic reaction until July 13, however, when the family told the physician that the patient was allergic to Haldol. Therefore no quality of care concern has been found for this stated complaint.

Based on a review of the medical documentation regarding this concern, we determined that the services received **did** meet all applicable professionally recognized standards of health care.

Your Concern:

- ❑ You state your mother was given Zyprexa after the family requested she not be given this medication.

VHQC Review Findings:

According to the medical record for this hospitalization, your mother intermittently became confused, agitated, and hallucinatory. During these episodes, she pulled out her feeding tube and Foley catheter, and pulled off her oxygen mask. A physician evaluated your mother again on July 12, 2011. He noted her confusion and agitation and ordered Zyprexa by injection because the family requested that your mother not receive Haldol or Seroquel. Per the nursing note, the family was informed of the use of Zyprexa, and at that time the family requested that your mother not receive additional doses of Zyprexa. Per the medication administration record, your mother did not receive any additional doses of Zyprexa.

In the opinion of the VHQC physician reviewer, your mother was agitated and potentially at risk for harming herself. The physician did not order Haldol or Seroquel per the family's request. Your mother required medication to decrease her agitation as this may also pose a cardiovascular risk. The physician was acting in good faith to help settle your mother and decrease self-harm. Therefore no quality of care concern has been found for this stated complaint. Based on a review of the medical documentation regarding this concern, we determined that the services received **did** meet all applicable professionally recognized standards of health care.

Your Concern:

- ❑ You state your mother was given Neurontin after the family requested she not be given this medication.

VHQC Review Findings:

Neurontin was ordered postoperatively. In the psychiatric evaluation of July 7, 2011, the physician noted that your mother was showing symptoms of delirium. According to the family, your mother's symptoms were similar to this when she had taken Lyrica in the past. On July 7, the physician ordered that the Neurontin be discontinued. Per the medication administration record (MAR), your mother did not receive any doses of Neurontin after this was discontinued.

In the opinion of the VHQC physician reviewer, it does not appear that your mother received additional doses of Neurontin once the family requested it be discontinued. Therefore, no quality of care concern has been found for this stated complaint.

Based on a review of the medical documentation regarding this concern, we determined that the services received **did** meet all applicable professionally recognized standards of health care.

Your Concern:

- ❑ You state your mother was given Seroquel after the family requested she not be given this medication.

VHQC Review Findings:

Per the medical record, on July 12, 2011 Seroquel 25 mg at bedtime was ordered for your mother. Per the MAR, she received one dose on July 12. Your mother did not receive a dose on July 13 because she was not taking anything by mouth. On July 14, at the family's request, the physician met with your mother's husband. The physician's note of 4:20 pm indicated that your mother was still quite confused and he increased the Seroquel dosage. His note reflected that Seroquel in low doses can cause sedation, but a higher dose does not. According to the record, the physician re-evaluated your mother at 9:40 pm on July 14 and noted the "family requests not to use Seroquel." The Seroquel was discontinued before your mother received any further doses.

In the opinion of the VHQC physician reviewer, it does not appear that your mother received additional doses of Seroquel once the family requested it be discontinued. Therefore, no quality of care concern has been found for this stated complaint.

Based on a review of the medical documentation regarding this concern, we determined that the services received **did** meet all applicable professionally recognized standards of health care.

Your concern regarding the care your mother received August 17, 2011 through August 18, 2011 at Inova Fairfax Hospital:

Your Concern:

- ❑ You state your mother was septic and it was not diagnosed during this inpatient stay.

VHQC Review Findings:

Per the medical record, your mother was transferred from a skilled nursing facility to the Inova Fairfax Hospital Emergency Department (ED) on August 17, 2011 with severe chest pain and shortness of breath. Her past medical history was significant for recent lumbar surgery, paralysis, rheumatoid arthritis, pulmonary fibrosis, and chronic obstructive pulmonary disease (COPD). She was receiving rehabilitation at another facility when she was transferred to the ED.

Per the ED notes, your mother reported her pain was worse when taking deep breaths. Her chest x-ray revealed a right-sided pleural effusion. A pleural effusion is a build-up of fluid between the layers of tissue that line the lungs and the chest cavity. Her white blood cell (WBC) count was elevated, indicating an infection. A CTA of her chest showed evidence of her recent lumbar surgery, and a nodule in the left upper lobe of her lung that measured 2.1 cm x 1.0 cm. The lymphadenopathy measured 3.0 cm x 2.2 cm. Her lab work was negative for a heart attack. Intravenous antibiotics, Vancomycin and Zosyn, were administered in the ED and your mother was admitted for further treatment.

The History & Physical for this admission showed that your mother had an elevated WBC, but no fever or other symptoms of an infection. The physician did not suspect pneumonia and noted your mother had received antibiotics in the ED. Another antibiotic, Rocephin, was ordered empirically until her symptoms improved. Both pulmonary and cardiac consultations were completed. Per the record note of August 18, the family requested that your mother be discharged and the physician agreed to discharge her. Your mother was evaluated before her discharge and it was noted that her chest pain had resolved. The medical record documentation indicated that her symptoms were likely due to fluid overload secondary to congestive heart failure. She was started on Lasix, a diuretic drug that reduces fluid retention. A urinalysis was also completed before your mother was discharged and the results showed she had white blood cells in her urine, too numerous to count, but her urine culture was negative.

In the opinion of the VHQC physician reviewer, the medical record revealed that your mother's vital signs were stable. A urinalysis was completed and the urine culture did not grow any organisms to confirm a urinary tract infection. The VHQC physician reviewer thus believes that the medical record documentation does not reveal or support a diagnosis of sepsis. Therefore, no quality of care concern was found for this stated complaint.

Based on a review of the medical documentation regarding this concern, we determined that the services received **did** meet all applicable professionally recognized standards of health care.

Your concerns regarding your mother's care at Inova Fairfax Hospital from August 29, 2011 through September 27, 2011:

Your Concern:

- ❑ You state your mother was septic and it was not diagnosed during this hospital stay.

VHQC Review Findings:

Per the medical record, your mother was transported back to the Emergency Department (ED) for shortness of breath and severe respiratory distress on August 29, 2011. She was placed on biPaP ventilation to help keep the upper airways of the lungs open by providing a flow of air delivered through a face mask. Her white blood cell count was elevated, indicating she had an infection. She was given intravenous (IV) steroids and IV antibiotics in the ED. She had an impaired cough due to her paralysis and was noted to be extremely debilitated. She continued on IV antibiotics, Vancomycin and Zosyn. In the History & Physical for this admission, the physician documented that he discussed your mother's treatment plan in detail with the family, and noted that her condition was extremely guarded. On admission, it was noted that your mother had a sacral decubitus ulcer. She experienced periods of confusion and agitation, and required and received intermittent tube feedings until she was able to take oral food and fluids safely. Your mother was discharged and transported to a skilled nursing facility in Florida on September 27, 2011.

According to the medical record, your mother was diagnosed with a urinary tract infection (UTI) on admission and was prescribed IV antibiotics for her UTI and for possible pneumonia. The record reflected that on September 2, 2011, your mother was evaluated for the management of her infection by an infectious disease physician who recommended changing her antibiotics and her urinary catheter. During the course of her stay, your mother developed a second UTI. Again, sensitivity testing was completed and she was started on antibiotics.

The VHQC physician reviewer noted that on presentation to the ED, your mother's heart rate was elevated and she was ill-appearing. Per the ED record, the ED physician noted "likely pneumonia/sepsis." Urine, blood and sputum cultures were obtained and broad coverage IV antibiotics were initiated. According to the record, your mother was treated by an infectious disease physician who made changes to her antibiotics based on culture and sensitivity results. It appears from the record that your mother was diagnosed during her stay with a recurrent UTI, which was initially treated with Ciprofloxacin until the sensitivity results were available.

In the opinion of the VHQC physician reviewer, it appears your mother had multiple medical problems and evaluation for infection was pursued when she did not show improvement and was experiencing increased confusion. Although your mother was not diagnosed with "sepsis" during her stay, it appears cultures were obtained and she was started on antibiotics when indicated. Therefore, no quality of care concern has been found for this stated complaint.

Based on a review of the medical documentation regarding this concern, we determined that the services received **did** meet all applicable professionally recognized standards of health care.

Your Concern:

- ❑ You state your mother's discharge summary did not contain information regarding her lung nodule.

VHQC Review Findings:

A CTA was performed on September 11, 2011. Per the CTA report, these results were compared to the CTA that had been done on July 10, 2011. The more recent image revealed a "new moderate/large effusion (fluid in the lung). Nodule now measuring 2.5 cm x 1.6 cm." Your mother's discharge summary did not contain information regarding the lung nodule or need for follow-up.

In the opinion of the VHQC physician reviewer, your mother's physician did not provide any information in the discharge summary about her lung nodule or the new findings from the CTA, and did not make any recommendations for follow-up care. Having this information in the discharge summary would have allowed for the next physicians involved in your mother's care to be aware of these findings. Therefore, this quality of care concern has been confirmed.

Based on a review of the medical documentation regarding this concern, we determined that the services received **did not** meet all applicable professionally recognized standards of health care. We share your concern about the quality of service your mother received.

However, in the opinion of the VHQC physician reviewers who reviewed this concern, who are board-certified in Oncology and Pulmonology, it was appropriate not to pursue additional testing related to the nodule because your mother was critically-ill during this hospitalization and further evaluation was not urgent.

Your Concern:

- ❑ You state your mother was not provided nutrition for eight days.

VHQC Review Findings:

Per the MAR, IV fluids were ordered on August 29. On August 31, 2011, your mother was started on a clear liquid diet and her IV fluids were changed to an electrolyte-replacing solution. On August 31, an order for speech therapy was written to evaluate your mother for the risk of aspiration, or accidentally inhaling liquids or food into her lungs. On September 1, it was noted that your mother had a slight cough after taking her medications and a swallowing evaluation was ordered, noting if your mother did not pass the evaluation, she would need tube feedings for nutrition. The notes also indicated your mother was sedated and lethargic. According to the medical record, the speech therapist made three attempts to perform a swallowing evaluation on your mother on September 1 and 2, but the family requested that your mother not be awakened for this test. The swallowing study was completed on September 3. Per the note, when the therapist arrived in the room, the family was giving your mother apple juice. The

therapist determined that it was unsafe for your mother to take oral fluids due to overt signs and symptoms of aspiration. The therapist recommended your mother have nothing by mouth except ice chips, that she receive her medications crushed in applesauce, and that she be placed on tube feedings as her primary source of nutrition. The therapist noted that the daughter was agreeable to tube feeding.

The medical record indicated that the feeding tube was placed later on September 3, and an x-ray to confirm the placement was completed on September 4. Tube feedings were started later on September 4. On September 7, the speech therapist advanced your mother's diet to mechanical soft with thin liquids. A mechanical soft diet includes foods that are mechanically altered so that they are soft and easy to chew and swallow. Thin liquids are those with a low viscosity and are "thin" in nature such as water and coffee. Her diet was changed to soft with thin liquids on September 8. The record indicated that on September 9, your mother was eating food brought in by the family. On September 10, the speech therapist recommended to increase the tube feedings and to run them at night as your mother's daily oral intake increased. On September 12, the record indicates your mother was taking a mechanical soft diet with thin liquids.

Per the physician note of September 13, your mother was tolerating her mechanical soft diet. According to the note of September 14, your mother pulled her feeding tube out and it was not replaced because she was eating 25-75% of her diet by mouth.

On September 19, your mother became less responsive and would not swallow. Because of your mother's change in mental status, the physician did not want her to have anything by mouth. The dietitian also noted that your mother could not safely take anything by mouth at that time. The medical record indicated that your mother's feeding tube was reinserted on September 20. The record reflected that several hours after her feeding tube was replaced, your mother pulled it out while under the supervision of the sitter and her husband. On September 21, your mother's diet was advanced to pureed and her feeding tube was replaced. By September 22, the dietitian noted your mother was more alert, talkative, drinking Ensure, and was tolerating a mechanical soft diet with thin liquids again.

According to the VHQC physician reviewer, it does appear that your mother lost approximately 18 pounds during this hospital stay, and several factors may have contributed to her weight loss, including the use of diuretic (fluid pills) medications. However, the medical record supports efforts by nursing, speech therapy and the physicians in an attempt to improve your mother's nutrition while balancing the changes in your mother's symptoms (agitation, delirium, pneumonia and tachycardia, or rapid heart rate). At times, your mother was able to eat and other times, she required tube feedings. Speech therapy re-evaluated your mother frequently and made several recommendations regarding supplemental and nightly feedings. The physician notes also supported continuing tube feedings in an effort to support your mother's nutritional needs.

Overall, in the opinion of the physician reviewer, your mother's nutrition was reassessed and adjusted as needed during her stay. Your mother may not have been able to eat during

episodes of agitation, but tube feedings were implemented to support her nutritional needs. There was no documentation found to support that your mother was not provided nutrition for eight days. It was further noted that at the time of admission to the rehabilitation facility, your mother was not below her ideal body weight. Therefore, no quality of care concern was found for this stated complaint.

Based on a review of the medical documentation regarding this concern, we determined that the services received **did** meet all applicable professionally recognized standards of health care.

Your Concern:

- ❑ You state your mother developed a decubitus ulcer.

VHQC Review Findings:

Per the medical record, your mother had a decubitus ulcer on her coccyx/anal area on admission to the hospital from the nursing home. In the wound nurse's note of August 29, 2011, the wound was described as a buttock/sacral ulcer, present on admission. "Very thick wound with about 10 cm x 9 cm area of dark red blanchable erythema on bilateral buttocks and lower sacrum. A healing ulcer is noted within the erythemous area on the sacrum measuring 2.5 cm x 2.0 cm, very shallow with epidermal bands noted. On the right edge a faint purple area is noted, 1 cm x 0.5 cm consistent with deep tissue injury. Scant serosanginous drainage from the open ulcer. Xenaderm ointment every 12 hours and mediplex dressing. Turn every two hours, dolphin bed." The documentation reflects these findings were discussed with the nurse and the patient's daughter.

On September 9, per the "Skin Assessment Sheet," your mother's sacral wound measured 2.5 cm x 3.0 cm x 0.5 cm with 90% healthy pink granulation tissue with deep tissue injury and black eschar, Stage II. There was no drainage or odor. Also on September 9, the pulmonologist noted during her evaluation that your mother had a Stage IV decubitus ulcer on her sacrum measuring 1.5 cm, with a 6 cm area of redness surrounding it. On September 14, the certified wound nurse described the ulcer as 1.5 cm x 1.0 cm, shallow, no odor, and scant drainage. The wound bed had greenish/yellow tissue. The nurse noted the dressing changes would remain the same, as the wound was healing. According to the palliative care note of September 19, "per the husband, worsening decubitus with more open tissue and change in color." On September 20, the wound nurse noted, "last seen September 14, wound measurements unchanged...Continue present wound care." On September 26, the wound nurse described the ulcer wound as "6 cm x 2 cm x shallow. Has open ulcer at sacrum 2 cm diameter with yellow bases darker area 4 cm surrounding. Surrounding tissue is pink and blanchable."

In the opinion of the VHQC physician reviewer, there appears to be a discrepancy in the medical record regarding your mother's sacral decubitus ulcer, which was present when she was admitted. The pulmonologist noted on September 9 that the patient had "developed a Stage IV decubitus ulcer over the course of multiple hospitalizations. Her sacrum reveals a grade IV decubitus of 1.5 cm breakdown with a 6 cm diameter; it is clean and getting treated

with Xenaderm." The wound care consult dated August 29 does not describe the decubitus as a Stage IV, but noted the ulcer was healing on the sacrum, 2.5 cm x 2 cm. The wound care consultant did not stage the wound and the dimensions did not appear consistently documented on follow-up wound care visits. Further, as noted above, on September 19 your mother's husband expressed to the palliative care staff that the wound was "worsening" and the September 20 evaluation by the certified wound nurse noted no change. Per the medical record, there appeared to be an increase in the size of the sacral wound from September 20 to 26. Based on the documentation submitted by the hospital, the sacral ulcer was 2.5 cm x 2.0 cm on September 20, then measured 6.0 cm x 2.0 cm with an open base six days later.

It appears that each wound assessment was not clearly documented by the certified wound nurse. Formal wound care assessment forms were not found in the medical record. Use of these forms to record ulcer location and size would have provided nurses and doctors with a tool to easily evaluate and monitor the healing of your mother's wounds. With the noted increase in the size of the sacral ulcer, there appeared to be no documentation of a change in the care plan, such as increased wound care or therapy. Further, no explanation for the increase in the size of the wound was found in the record. Therefore, this quality of care concern has been confirmed for the hospital.

Based on a review of the medical documentation regarding this concern, we determined that the services received **did not** meet all applicable professionally recognized standards of healthcare. We share your concern about the quality of service your mother received.

Your Concern:

- ❑ You state your mother was restrained illegally during this admission.

VHQC Review Findings:

Per the medical record, your mother's wrists were restrained periodically during this stay for her own safety. The record reflects that your mother was intermittently agitated, hallucinatory, confused, and combative. She repeatedly pulled out the PICC intravenous line (peripherally inserted central catheter), feeding tube, and Foley catheter, even when family and staff were present; all of which had an impact on her care. She would also try to pull off her heart monitoring equipment. According to the record, your mother was given a dose of Ativan on September 15 for agitation, but it was not effective. On September 21, the physician wanted to order Haldol for your mother's agitation, but the family declined. Your mother's physician was notified and orders were received to apply physical restraints. Medical record documentation supports the need for restraints, as do assessments of your mother while she was restrained. The notes indicate the family was informed when your mother was placed in restraints and told of the reasons she was being restrained.

In the opinion of the VHQC physician reviewer, it appears that limb restraints were utilized only in periods in which your mother was agitated or combative. Medical record documentation supports that your mother pulled out her PICC line and feeding tube on several occasions. At

those times, the feeding tube was her primary source of nutrition. While the restraints were in use, your mother was checked by nursing staff every two hours per protocol. Further, it does not appear that the restraints were used inappropriately. Prior interventions were attempted without success, such as medications to calm her, and the least restrictive devices were utilized. Therefore, no quality of care concern was found for this stated complaint.

Based on a review of the medical documentation regarding this concern, we determined that the services received **did** meet all applicable professionally recognized standards of health care.

We are unable to provide any additional information that explicitly or implicitly identifies the involved practitioners because applicable federal regulations prohibit the release of such information without the involved practitioners' consent. Even though we are unable to provide a more detailed explanation of our review findings, please be assured that your concerns were thoroughly evaluated. In addition to determining whether or not care met professionally recognized standards of health care, we have reviewed the medical records pertaining to the services provided to your mother to see if there were any opportunities for improvement. Please be assured that if opportunities for improvement were identified, the VHQC took appropriate measures to address these opportunities.

QIO Plan of Action: Quality Improvement Initiative

Based on our findings of a delay in testing prior to the July surgery, the lack of information on the discharge summaries regarding the lung nodule, and the development, assessment and care of the decubitus ulcer, VHQC is asking the involved physicians and hospital to participate in quality improvement initiatives with us to help ensure that future patients do not experience the same concerns that affected your mother's care. These initiatives involve focused work to re-design and improve patient care processes and systems, so by bringing your concerns to our attention, you have helped improve health quality for many other patients and their families.

The effectiveness of communication between health care providers and a patient and his/her family is important in engaging patients and families in decision making, and in shaping the patient and family's perceptions of, and satisfaction with, a health care experience. When communication is not effective, the patient and/or family's expectations of clinical services may not be met, even when the care provided is appropriate to the patient's medical needs. The effectiveness of communication between providers, patients and families often cannot be determined by a review of the medical record.

The information in this notice is confidential and may be re-disclosed only in accordance with Federal regulations found in 42 CFR Part 480.

This letter completes our review and constitutes our final determination on the concerns that were raised. We appreciate the opportunity you have provided us to continue to ensure that people with Medicare receive quality medical care. If you have any questions, please contact:

Jennifer Day, RN
Clinical Review Specialist
VHQC
9830 Mayland Drive, Suite J
Richmond, VA 23233
1-800-545-3814

Sincerely,

Sallie S. Cook, M.D.
Chief Medical Officer
SSC/jd

INOVA

Inova Fairfax Medical Campus

December 10, 2012

Jennifer Day, RN
Clinical Review Services Manager
VHQC
9830 Mayland Drive, Suite J
Richmond, VA 23233

Dear Ms. Day:

This letter is in response to your letter dated November 21, 2012. We thank you for the opportunity to review and respond to the proposed correspondence to Debra Van Putten. With regard to the confirmation of the quality of care concern related to the completion of certain radiologic tests during the July 1, 2011-July 21, 2011 admission, Inova offers the following response: all care and tests provided to Mrs. Van Putten were in accordance with the professional judgment of the clinicians involved and Inova believes such care was appropriate.

Thank you,

Patrick Christiansen, Ph.D.
Chief Executive Officer
Inova Fairfax Medical Campus

Patrick L. Christiansen, Ph.D.
Chief Executive Officer
Executive Vice President
3300 Gallows Road, Falls Church, VA 22042
P 703.776.3050 F 703.776.3623
www.inova.org